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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/803,406

03/17/2004

Thomas Weisel

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03/20/2007

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EXAMINER

NGUYEN, TUAN VAN

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

03/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/803,406

Applicant(s)

WEISEL ET AL.

Examiner

Tuan V. Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 15-27 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11,12 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10,13,15-17 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 18-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after the final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2007 has been entered.

Specification

2. According to the submission filed on February 26, 2007, Applicant amended the Abstract to overcome previous objection, therefore, the Objection is hereby withdrawn.

Response to Amendment

3. Applicant's arguments filed on February 26, 2007 with respect to 102(b) rejection based on Toy reference have been fully considered but they are not persuasive. With respect to arguments regarding claims 1, 13 and 22, which are currently amended, that applicant has explicitly amended the limitation "unitary", thusly, Toy reference does not teach this limitation. Examiner respectfully traverses the applicant's remarks: Toy clearly discloses a needle assembly comprising: the needle shaft 3 or actuating rod, the pointed head 6 or sharp distal tip, the hook 8, and the latch 9 or gathering arm, bifurcated portions, which is located between the

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shoulder or hook 8, latch 9 or gathering arm and the bottom portion of needle shaft that connected to the sharp needle tip 6 or the backing arm, are fabricated from a single piece of 174-PH grade stainless steel (see col. 4, lines 33-36).

4. Applicant's arguments filed on February 26, 2007 with respect to 102(e) rejection based on Chu reference have been fully considered and persuasive, therefore, the rejection is hereby withdrawn.
5. Applicant's arguments filed on February 26, 2007 with respect to 102(e) rejection based on Diduch reference have been fully considered and persuasive, therefore, the rejection is hereby withdrawn.
6. Applicant's arguments filed on February 26, 2007 with respect to 103(a) rejection as obvious over Skiba reference have been fully considered and persuasive, therefore, the rejection is hereby withdrawn.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-7, 10, 13 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Toy et al (U.S. Patent 5,618,290). The entire document of Toy reference is applied to the rejection.**

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9. Referring to **claims 1-7, 10, 13 and 22-24**, Toy et al disclose a device (1, Figures 2-12) comprising: a hollow elongate shaft (11); a handle assembly (16 and 17) coupled to the shaft (11) wherein the handle assembly (16 and 17) is also a needle lock and having a releasable locking relationship with the needle; a thumb slide (17) moveable on the handle housing in a proximal and distal position relative to the needle assembly creating a free suture state when distal and a captured/locked state when proximal; an actuating rod (3, Figure 4) having a proximal end and distal end; a needle assembly (6, 7, 8, 9) disposed at the distal end of rod (3) movable back and forth with the actuating rod between an extended and retracted state; the needle assembly having unitary (clearly shown where 3 points in Figure 4) cylindrical bifurcated portions (backing arm 9 and gathering arm 7) defining a suture slot between; the arms (7, 9) are separate due to spring forces in the extended state and proximate/contacting due to shaft (11) in the retracted state; the needle assembly also comprising a sharp distal tip (6) integral with arm (7) (see col. 3, line 20 to col. 4, line 25). Furthermore, Toy discloses the needle shaft 3 or actuating rod, the pointed head 6 or sharp distal tip, the hook 8, and the latch 9 or gathering arm, bifurcated portions, which is located between the shoulder or hook 8, latch 9 or gathering arm and the bottom portion of needle shaft that connected to the sharp needle tip 6 or the backing arm, are fabricated from a **single piece** of 174-PH grade stainless steel (see col. 4, lines 33-36).
10. Referring to **claims 5-7**, it is noted that there are "portions" of each arm that meet the criteria as broadly claimed.

11. Referring to **claims 22-24**, Figures 6-12 and claims 16-19 clearly demonstrate the method as claimed.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. **Claims 15-17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toy in view of Trott (U.S. Patent 5,312,422). The entire document of Toy and Trott references applied to the rejection.**

15. Referring to claims 15-17 and 21, Toy discloses the invention substantially as claimed except for the thumb slide is operated such that in the distal position is associated with the free suture state, the proximal position is associated with the

captured suture state, and that a ratchet mechanism is used to lock the relationship of the needle.

16. Still referring to claims 15-17 and 21, however, Trott disclosed such a device. Trott discloses a suturing needle (see Figs. 1, 8 and 9) comprising: bifurcated needle assembly 14, among other things, connected to push block 4 that positioned inside handle 2; thumb switch 6, which includes push block 4 and ratchet mechanism for locking of the needle assembly 14, connected to handle 2 wherein user slides the thumb switch distally to open the bifurcated needle for loading the suture or capturing the suture and slides the thumb switch in the proximal direction to capture the suture (see col. 3, lines 5-35 and col. 4, line 39 to col. 5, line 9).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made by the applicant to incorporate the handle design and the locking mechanism, as disclosed by Trott, to incorporate into the device, as disclosed by Toy in order to gain the advantage of providing ergonomic and positive locking mechanism as suggested by Trott.

Allowable Subject Matter

17. Claims 18-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tuan V. Nguyen whose telephone number is 571-272-5962. The examiner can normally be reached on M-F: 9:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, AnhTuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tuan V. Nguyen
March 14, 2007


ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
